

### **REMARKS**

This Amendment is made in response to the Official Action mailed December 12, 2008. A request for a one-month extension of time accompanies this Amendment. Claims 1-32 remain pending in this application. Reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the following remarks.

Preliminarily, Applicants note that paragraph 12 of the Official Action Summary page, indicates that "Some", but not "All" of the documentation for the claim for priority under 35 U.S.C. §119(a)-(d) or (f), have been received. Applicants would appreciate clarity regarding what additional supporting documentation is required since certified copies of the priority documents have already been received.

In addition, Applicants note that claims 1-32 have been rejected under the non-statutory doctrine of obviousness-type double patenting, as being unpatentable over the claims of U.S. Patent Application No. 12/088,661. While Applicants do not admit that the instant claims are indeed obvious over the claims of U.S. Patent Application No. 12/088,661, Applicants will consider filing a terminal disclaimer if and when claims in either case are deemed allowable.

Claims 1-32 have been rejected under 35 U.S.C §103(a), as being unpatentable over WO95/32948, published December 7, 1995, to Farina et al. ("Farina") in view of U.S. Publication No. 2002/0056206, May 16, 2002, to Pace et al. ("Pace"). In particular, the Action asserts that Farina discloses talnetant as a useful pharmaceutical agent, NK-3 antagonist and for treating pulmonary, CNS and neurodegenerative disorders. The Action admits that Farina does not teach the process of preparing the pharmaceutical composition with bulking agents or excipients such as surfactants and carriers. Secondary document Pace is used for teaching the process of preparing spray dried pharmaceutical agents with different bulking agents. Reconsideration and withdrawal of the rejection are respectfully requested.

Talnetant is poorly soluble in the aqueous media found in the gastrointestinal tract ("GIT"). To improve solubility it is well known to maximize the surface area for absorption by ensuring that very small particles are present in the GIT. The problem the inventors experienced was that spray drying suspensions of very small solid particles resulted in agglomeration. There were numerous attempts to avoid the problem of agglomeration on spray drying. The problem was eventually solved by incorporating an ionic surfactant in the suspension of solid particles to be spray dried. As can be seen from Table 1, suspensions containing ionic surfactant resulted in virtual 100% recovery of particle size. In contrast, use of a non-ionic surfactant

resulted in poor recovery. This was a major step forward in the development of talnetant as a potential drug.

The Action cites Pace against the above application and points to disparate points in the disclosure that are argued to render the invention obvious. Applicants respectfully disagree. The skilled person reading Pace would clearly understand that it relates to spray drying aqueous emulsions of molten fenofibrate containing "microdroplets". Pace teaches that the presence of a specific surface active agent phospholipid, helps prevent the molten droplets of fenofibrate in vigorously-agitated hot emulsions, from coalescing when heated to a temperature above the melting point of fenofibrate.

In contrast, the claims of this application relate to a process, and composition made thereby, of spray drying suspensions of solid particles. Applicants urge that the skilled artisan reading the teaching of Pace relating to (i) hot, (ii) molten, and (iii) liquid emulsions, would not have applied that teaching to the instant invention of (i) suspensions of (ii) solid particles at (iii) room temperature, as defined in the claims. Therefore, a prima facie case of obviousness has not been made. Favorable reconsideration of the rejection under Section 103(a) is requested.

In view of the foregoing, favorable reconsideration of claims 1-32 and allowance of this application are earnestly solicited.

Respectfully submitted,



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